Broad Agency Announcement

No. BAA-NIAID-DMID-NIH-AI-2014028

Title: Targeted Clinical Research to Address Select Viral Infections

Issue Date: December 15, 2014

Due Date: May 12, 2015

Issuing Office: Office of Acquisitions, Division of Microbiology and Infectious Diseases, DEA, NIAID, NIH, 5601 Fishers Lane, Room 3D32, MSC 9821, Bethesda, MD 20892-9821

Contracting Officer: George W. Kennedy, kennedyg@niaid.nih.gov

Contact Point/ Contract Specialist: Swee Teo, teosl@niaid.nih.gov

Set-Aside: No

It is requested that you send an early electronic mail message to the Contract Specialist if you intend to respond to this BAA. In your message please indicate the name of the organization, address, telephone, and include the name of the Principal Investigator, plus a short description of the scientific fields encompassed by the response.

I. INTRODUCTION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA). The BAA is governed by Federal Acquisition Regulation (FAR) 6.102 and FAR 35.016, as well as the NIH Policy Manual, Manual Chapter 6035, Broad Agency Announcements. A BAA may be used as a solicitation mechanism for basic and applied research directed toward advancing the state-of-the-art or increasing knowledge or understanding and that part of development not related to the development of a specific system or hardware procurement. BAAs are general in nature identifying areas of research interest and shall only be used when meaningful proposals with varying technical/scientific approaches can be reasonably anticipated. Offers submitted in response to this BAA must present detailed technical and business proposals designed to meet the Research and Technical Objectives described herein. The Statement of Work (SOW), including the specific technical requirements and performance specifications, shall be developed and proposed by the offeror, not the Government.

Since they are not submitted in accordance with a common SOW issued by the Government, proposals are NOT evaluated against each other. Instead, Research and Technical Objectives are provided in the BAA that describes the research areas in which the Government is interested. Proposals received in response to the BAA will be evaluated in accordance with Evaluation Factors for Award specified in Section VIII of this document.

Multiple awards are anticipated. The amount of resources made available under this BAA will depend on the quality of the proposals received and the availability of funds. The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this BAA, and to make awards without discussions with offerors. The Government also reserves the right to conduct discussions, if it is later determined to be necessary. Additionally, the Government reserves the right to accept proposals in their entirety or to select only portions of proposals for award.

In the event the National Institute of Allergy and Infectious Diseases (NIAID) decides to award only portions of a proposal, negotiations may be opened with that offeror. The Government reserves the right to fund proposals in phases with options for continued work at the end of one or more of the phases.

NIAID estimates that three to five contracts may be issued for a total cost (direct and indirect costs combined) of up to $6.3 million in Fiscal Year 2016 for all awards during the first non-severable phase. Awards are expected to be made on or about May 1, 2016. It is anticipated that the total costs for each award may vary depending upon the scope and capacity of the technical objectives of the award. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. The total period of performance comprised of a base period and options proposed by an offeror should not exceed five (5) years.

II. BACKGROUND AND TECHNICAL OBJECTIVES

A. Background

Research supported and conducted by NIAID, National Institutes of Health (NIH), Department of Health and Human Services (DHHS), strives to understand, treat and ultimately prevent the myriad of infectious, immunologic, and allergic diseases that threaten the health and lives of millions of humans. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents, with the exception of the human immunodeficiency virus (HIV). This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics, which are funded through a variety of research grants and contracts.

Rare and/or emerging viral diseases typically are associated with significant morbidity and mortality and economic costs worldwide. A rare (or orphan) disease is generally considered to have a prevalence of fewer than 200,000 affected individuals in the United States. Emerging viral diseases can be defined as infections that have newly appeared in a population, or have existed but are rapidly increasing in incidence in that population or geographic range.

Although many of the disease syndromes (conditions and manifestations) caused by viruses in general are relatively benign and self-limited in the normal host, they are often much more severe in a variety of special populations of patients, e.g., immunocompromised individuals, the elderly, pregnant women, or children and neonates. The study of serious rare or emerging viral infections in these populations provides unique and special challenges and treatment options are frequently sparse. Consequently, the development of effective therapies or therapeutic strategies for rare viral diseases or viral diseases in special populations remains a significant unmet medical need. The pharmaceutical industry is focused primarily on the development of therapies for chronic viral infections, such as HIV, hepatitis B, hepatitis C or therapies for acute viral illnesses that are usually self-limited, but

may affect large numbers of people, such as influenza or the common cold. Whereas, the development of therapies for rare and/or emerging viral diseases has not been an industry priority due to potentially limited markets, high development costs and/or because knowledge on the natural history of the illness is limited. Natural history studies that focus on understanding the range of manifestations, disease progression, disease presentation in various populations and the establishment of biomarkers of clinical progression and correlates of clinical outcome are being recognized as critical to facilitate effective product development programs and overcome issues that have led to stalled or failed product development strategies.

B. Technical Objectives

The overall objective of this solicitation is to support/advance the development of therapeutic strategies for rare and/or emerging viral diseases (non-HIV) of medical importance in targeted patient populations. The NIAID is aware that many of these diseases, and the patient populations that are most affected, may not be amenable to traditional product development/common clinical trial methodologies. Thus, the evaluation of the natural history, as well as the use of alternative and innovative research methods and clinical trial design strategies, is encouraged, where appropriate and valid. A variety of clinical study approaches will be considered responsive including natural history studies, retrospective analysis of existing data (either in patient records or other patient data registries), and interventional clinical trials. Adaptive clinical trial designs (http://www.fda.gov/downloads/Drugs/.../Guidances/ucm201790.pdf) or other alternative clinical trial designs with adaptive features are encouraged, when appropriate. The assessment of laboratory surrogate markers for clinical response, enhanced use of existing therapies, evaluation of new therapeutic drugs and the development of resistance to important antiviral drugs are important aspects, and may be included in any study proposed.

For the purposes of this BAA, the targeted patient populations are those for which there is a significant unmet medical need for therapeutic options for rare/emerging viral diseases that are not being addressed by the pharmaceutical industry or other significant clinical initiatives. Targeted populations include children (neonates through adolescents); the elderly, transplant recipients, and pregnant women. Studies in the general population may be considered for select rare and/or emerging diseases (see below).

Natural history studies are defined as those that evaluate the contemporary clinical course of the viral disease in a target patient population, with the goal of providing data to design interventional clinical trials. Important aspects include evaluation of a disease's incidence, variability in patients, causes of morbidity and mortality, and response to standard of care. Studies that focus primarily on immunologic changes associated with disease progression will not be considered.

The following are some examples of research areas of interest:

In pediatric subjects, viral diseases that are considered to be rare would include, but are not limited to: congenital cytomegalovirus (CMV), serious enteroviral diseases, Epstein-Barr virus (EBV) infections, neonatal herpes virus infections, and serious flavivirus or filovirus infections. However, diseases such as influenza in pediatric patients would not be considered rare.

Viral infections are increasing in incidence in transplant patients, as immunosuppressive therapies improve in potency. Epstein Barr virus (EBV), human herpesvirus-6 (HHV-6) and adenovirus infections are a few examples of infections following transplantation. Norovirus infections are posing an increased risk for serious outcomes in vulnerable populations, such as the elderly and transplant recipients. Viral infections of the nervous system, specifically viral encephalitis (various viral etiologies), are examples of rare diseases with significant morbidity in the general population. Finally emerging diseases such as serious flavivirus, lassa fever virus, and chikungunya virus infections, remain, to date, rare in the US, but have the potential to cause significant morbidity/mortality. In these cases, international studies may be necessary.

For the purposes of this BAA, eligible clinical trials/studies include:

- Interventional trials of safety and effectiveness for treatments for rare and/or emerging viral diseases (non-HIV) of medical importance in targeted patient populations and under-served by the pharmaceutical industry (Phase I [except first in human studies], Phase II or Phase IV are allowable);
- Natural history studies of the rare and/or emerging viral diseases to assist in the design of treatment trials with useful endpoints;
- Validation of biomarkers or surrogate markers of clinical responses and safety in antiviral therapy for the purposes of designing future clinical therapeutic studies;
- Validation of diagnostic tests for predicting clinical response to therapy;
- Proof of principle studies to further product development;
- Exposure/exposure-response studies (using pharmacokinetic and pharmacokinetic /pharmacodynamic approaches) to optimize therapies;
- Assessment of the emergence of resistance to antiviral therapies; or
- Analysis of existing databases or patient charts.

Contracts awarded under this BAA will **NOT** support:

- Surveillance studies;
- Transmission studies;
- Studies of vaccines;
- Studies designed primarily to evaluate the immunologic changes associated with the viral disease;
- Studies designed to evaluate immunosuppressive regimens in transplant patients;
- First in human (FIH) interventional trials;
- Phase III studies;
- HIV studies or studies of other infections in HIV patients;
- Studies for viral illnesses for which there are effective marketed therapeutics or substantial pharmaceutical industry investment in development of therapies, such as influenza, hepatitis C or hepatitis B.

NOTE: Organizations responding to this BAA must have documented expertise in clinical research and clinical research in the patient population proposed or in the type of study proposed, and demonstrated knowledge of applicable regulatory guidelines.

III. GENERAL PROPOSAL INSTRUCTIONS AND INFORMATION

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other.

The Technical Proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions and total cost for the work (see http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf). Proposals should be direct and concise in presenting information which clearly describes the proposed project. Offerors should realize that a concise and well formulated proposal is usually more effective to communicate project ideas to reviewers versus a voluminous proposal that lacks effective distillation of ideas.

A. Proposal Submission

1. Receipt Date

The deadline for receipt of proposals submitted in response to this announcement is:

May 12, 2015, 3:30 PM EST

2. Proposal Submission

a. The National Institute of Allergy and Infectious Diseases (NIAID) currently requires proposals to be submitted via two methods:

1) Online
2) Disc (CD or DVD)

Notes:

- *Submission of proposals by facsimile or e-mail is not acceptable.*
- *Online and disc proposals must be exactly the same.*

3. Online Submission of Electronic Proposals

a. eCPS PROPOSAL SUBMISSION PROCESS

1) Offerors are required to submit an electronic copy of proposals online through the NIAID electronic Contract Proposal Submission (eCPS) website at https://ecps.nih.gov/.
2) Follow the "*How to Submit an Electronic Proposal"* instructions provided on the eCPS website at: https://ecps.nih.gov/NIAID/Home/howto.
3) Please note that creating an account to submit can take up to three (3) business days. Please register early to allow enough time for the registration process.

4. DISCS (i.e., CD or DVD)

a. Delivery Instructions

If Hand Delivery or Express Service	If using U.S. Postal Service
Mr. George Kennedy Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 5701 Fishers Lane, Room 3D32 MSC 9821, Rockville, MD 20852-9821	Mr. George Kennedy Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 5701 Fishers Lane, Room 3D32 MSC 9821, Bethesda, MD 20892-9821

1) Mark each package with the following items:

The solicitation number: *BAA-NIAID-DMID-NIH-AI-2014028*
"TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

2) All material sent to this office by courier should be sent to the Hand Delivery or Express Service address.

3) The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20852 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. The Government is not responsible for picking up any mail at a local post office.

4) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated above by the date and time specified in the solicitation. If your proposal is not received by the date and time specified in the solicitation, it will be considered a "late proposal", in accordance with **FAR Clause 52.215-1 Instructions to Offerors – Competitive Acquisition.**

b. Discs – Creating and Naming Files:

1) Create one PDF file of your Technical Proposal, including all attachments. The Technical Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Technical Proposal PDF file.

2) The Business Proposal must be comprised of the following two files:

a) The first file must be a PDF of your Business Proposal, with all attachments, including the Solicitation Section J, Attachment entitled "Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet" (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx). The Business Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring

signature(s) may be scanned and merged into the Business Proposal PDF file.

b) The remaining file(s) must be the "Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet" in its original Excel format, not PDF. Multiple Excel files may be included, as necessary.

3) A separate Disc must be submitted for the Technical Proposal and Business Proposal. *Offerors who submit both Technical and Business Proposals on the same Disc will be required to resubmit the proposals on separate Discs*.

4) **File naming convention**: It is required that the filenames for both your Technical Proposal, Business Proposal, and Excel Workbook include the name of the offeror, the solicitation number, and the type of proposal (i.e., Technical, Business, or Excel Workbook).

Examples:
Technical Proposal: *XYZ Company_NIHAI2014028_Technical_Date.pdf*
Business Proposal: *XYZ Company_NIHAI2014028_Business_Date.pdf*
Excel Workbook: *XYZ Company_NIHAI2014028_Business_Date.xlsx*

5. Formatting, Number of Copies, and Page Limitations

a. Formatting for discs and proposals submitted online through eCPS:

1) Proposals shall not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information;
2) Font size must be 10 to 12 points;
3) Spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text;
4) Margins must be at least one-inch on all sides;
5) **Failure to adhere to the formatting requirements above may impact whether your proposal is reviewed in its entirety.**

b. Number of copies and applicable page limitations:

1) Total page count does not include: Title and Back Page; Table of Contents; Section Dividers that do not contain information other than title of Section.
2) **Pages in excess of this limitation will be removed from the proposal and will not be considered.**

NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS

Document	Number of Copies	Page Limits
Technical Proposal	**ONLINE (using the eCPS website)** One (1) electronic copy of the Technical Proposal (including all Attachments) **DISC (i.e., CD or DVD)** One (1) Disc containing one electronic copy of the Technical Proposal (including all Attachments)	**Not to Exceed 75 pages (inclusive of all Attachments except CVs)**
Business Proposal	**ONLINE (using the eCPS website)** One (1) submission containing two files, as instructed below. a. One (1) electronic PDF copy of the Business Proposal (with all Attachments including the PDF rendering of the **Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet** (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx). b. One (1) Electronic Cost Proposal Excel Workbook **See a. above - Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.** Microsoft Excel 2007 version or later is required. **DISC (i.e., CD or DVD)** One (1) Disc containing two files, as instructed in Section III.A above.	N/A

B. NAICS Code and Size Standard

Note: The following information is to be used by the offeror in preparing its Representations and Certifications, specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541712.
(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS)

Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

C. Restriction on disclosure and use of data (January 2007) – FAR 52.215-1

(1) The proposal submitted in response to this request may contain data [trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data] which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data are not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes."

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act.

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement: "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

D. Communications Prior to Contract Award

Offerors shall direct all communications to the attention of the Contract Specialist cited at the beginning of this announcement. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

E. Release of Information

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

F. Preparation Costs

The Government will not pay for the preparation and submission of proposals.

G. Promoting Efficient Spending

On September 21, 2011, the Office of Management and Budget issued Memorandum M-11-35 , entitled, "Eliminating Conference Spending and Promoting Efficiency in Government," emphasizing the President's priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government (EO 13576) and the Executive Order on Promoting Efficient Spending (EO 13589). On January 3, 2012, the Department of Health and Human Services (DHHS) issued the memorandum "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing, and Publications" (See http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html).

In support of these directives, the NIH issued a January 30, 2012, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences, Conference Grants and Meetings, Food, Promotional Items, and Printing and Publications." (See http://www.hhs.gov/asfr/ogapa/acquisition/policies/promoting-efficient-conference-spending-policy-12-16-2013.html).

Any contract awarded as a result of this BAA will:

- Specifically prohibit the use of contract funds for the provision of food for meals, light refreshments and beverages for any NIH funded meeting or conference; and
- Limit the procurement of meeting space, promotional items, printing and publications for meetings.

H. Service of Protest (September 2006) - FAR 52.233-2

(1) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

George W. Kennedy, Contracting Officer
Division of Microbiology and Infectious Diseases Branch
National Institute of Allergy and Infectious Diseases
DEA, Office of Acquisitions
5601 Fishers Lane, Room 3D32, MSC 9821

Bethesda, MD 20892-9821

(2) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

I. Restriction on Pornography on Computer Networks

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

J. Gun Control

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

K. Institutional Responsibility Regarding Conflicting Interests of Investigators

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any conflicting financial interest of an Investigator. The Institution shall comply with all requirements of 45 CFR Part 94 at http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=c868ce44081bdf3d09de55d230c9b5b7&r=PART&n=45y1.0.1.1.51#45:1.0.1.1.51.0.19.4

L. Limitations on Use of Appropriated Funds

The Department of Health and Human Services Appropriation Act limits the use of appropriated funds on NIH grant, cooperative agreement, and contract awards as specified below. It is anticipated that these statutory provisions will continue in subsequent fiscal years and be incorporated into any award documents. If selected for negotiations, you will be provided all specific limitations concerning appropriated funds applicable at the time of negotiations.

1) Salary Limitations

(a) Pursuant to the current and applicable HHS appropriations acts, the Contractor shall not use contract funds to pay the direct salary of an individual through this contract at a rate in excess the Federal **Executive Schedule Level II** in effect on the date an expense is incurred.

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are collectively referred to as "direct salary" in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).
Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with Federal funds.

(c) The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish contract or order funding.

(d) See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

(End of clause)

See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/ .

(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / select Another Year at the top of the page / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

2) Restriction on Distribution of Sterile Needles

"None of the funds contained in this Act may be used to distribute any needle or syringe for the purpose of preventing the spread of blood borne pathogens in any location that has been determined by the local public health or local law enforcement authorities to be inappropriate for such distribution."

3) Restriction on Abortions

"(a) None of the funds appropriated under this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for any abortion. (b) None of the funds appropriated in this Act, and none of the funds in any trust to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortions. (c) The term "health benefits coverage" means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement."

4) Ban on Funding of Human Embryo Research

"(a) The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

5) Limitation on Use of Funds for Promotion of Legalization of Controlled Substances

"(a) None of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act except for normal and recognized executive-congressional communications. (b) The limitation in subsection (a) shall not apply when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage."

6) Dissemination of False or Deliberately Misleading Scientific Information

"None of the funds made available in this Act may be used to disseminate scientific information that is deliberately false or misleading."

7) Restriction on Employment of Unauthorized Alien Workers

The Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

8) NIH Public Access Requirement

"The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, that the NIH shall implement the policy in a manner consistent with copyright law."

Further information on the implementation of NIH's Public Access Requirement is available in NIH Guide Notice NOT-OD-08-033 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html) published on January 11, 2008.

IV. UNIFORM ASSUMPTIONS

For the purposes of estimating costs and preparing the technical proposal, the following POST-AWARD requirements will apply to all awards made under this BAA.

Offerors are instructed to address responsibility for complying with the following requirements in your proposed SOW. Offerors are NOT required to submit documentation to address these post-award requirements in their technical proposals.

Instructions for submitting documentation associated with post-award requirements will be provided during negotiations.

A. **Site Visit**: Assume five (5) independent site visits through the duration of the contract period of performance.

B. **Purchase of Equipment**: Costs will **NOT** be allowed for the purchase of any equipment, hardware, or software.

C. **Alterations and Renovations**: Costs will **NOT** be allowed for any facility construction, alterations, or renovations.

D. **Programmatic Presentations and Reviews**

In performance of the work, offerors are expected to attend the following reviews.

1. Post Award Contract Initiation Review

   In preparing the proposal, offerors should include costs for attendance at one Post Award Contract Initiation Review. Offerors should assume a one-day review will be conducted at/near Washington, D.C. or at the contractor site and attendance should include all Key Personnel.

2. Annual Contract Reviews

   In preparing the proposal, offerors should include costs for annual contract reviews. These reviews are anticipated to be held at the Contractor's facility and a location at/near Washington D.C. on an alternating-year basis. The reviews are anticipated to be one-day reviews. Offerors should include costs for the attendance of the Key Personnel.

E. **Clinical Protocol and Supporting Documents Development**

In the performance of the work of developing the final clinical protocol and subsequent revisions to that protocol, offerors should expect the following:

- A protocol team that includes representatives from DMID/NIAID
- Protocol standards as outlined in http://www3.niaid.nih.gov/LabsAndResources/resources/DMIDClinRsrch
- Final protocol approval from DMID/NIAID no sooner than 3-6 months after the initial protocol team meeting; typically 2-3 revisions may be required.
- DMID/NIAID safety oversight of interventional studies (see: http://www.niaid.nih.gov/LabsAndResources/resources/DMIDClinRsrch/Pages/safetyoversight.aspx)

F. **Clinical Protocol Implementation and Support Services requirements**

1. The contractor shall plan to attend 1-2 meetings by teleconference with the Contracting Officer's Representative (COR) and DMID clinical oversight personnel per month to discuss specific study related issues.

2. The contractor shall set up a study initiation meeting to provide training on the protocol for all clinical research sites prior to opening the study for enrollment.

3. The contractor and each participating clinical research site shall undergo an initial site assessment to ensure the adequacy of clinical research facilities, equipment and operating procedures, as well as appropriate training of clinical staff with respect to the conduct of human subjects research. Initial clinical site assessments will be conducted by DMID staff and/or DMID-designated entities (DMID-Clinical Research Management). The contractor shall make all relevant study personnel, documentation, facilities and equipment available for such assessments and shall implement any COR-approved corrective actions resulting from such assessments.

V. Reporting Requirements

A. In performance of the work, the following reporting requirements should be assumed:

1. Semi-annual Progress Report

This report shall include a description of the activities during the reporting period and the activities planned for ensuring reporting period. The initial report will be submitted for the first full six months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months. A semi-annual report will not be required for the period when an Annual Progress Report is due.

2. Annual Progress Report

This report includes a summation of the technical activities and results for the performance year covered. An Annual Progress Report will not be required for the period when the Final Report is due.

3. Post Award Contract Initiation and Annual Contract Reviews

A report of the Post Award Contract Initiation Review and Annual Contract Reviews shall be prepared by the Contractor and submitted within twenty-one (21) calendar days following the date of the reviews. These reports shall include the slide presentations and all other review materials, as well as summaries of all discussions.

4. Meetings and Teleconference Minutes

Minutes of regular, as well as *ad hoc*, meetings and teleconferences shall be provided by the Contractor within two (2) business days following the date of the meeting or teleconference.

5. Final and Draft Reports

This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. An annual report will not be required for the period when the Final Report is due. The

Contractor shall submit, with the Final Report, a Summary of Salient Results (not to exceed 250 words) achieved during the performance of the contract.

6. Draft and Final Clinical Protocols

The Contractors shall develop all necessary draft and final full Clinical Protocols in accordance with DMID clinical research policies, templates and requirements as specified at:
http://www3.niaid.nih.gov/LabsAndResources/resources/DMIDClinRsrch/ and coordinate protocol development activities with the COR. DMID final protocol approval will be required before implementation of any clinical research.

7. Draft and Final Clinical Research Supporting Documents

The Contractor shall be required to develop and submit to DMID for review and approval any documents necessary to support the conduct of the clinical research. Examples of documents that may be needed include, but are not limited to: patient consent forms; case report forms, documents to support the conduct of the study such as study manuals (procedures); a formal statistical analysis plan (for interventional clinical trials). The types of documents needed will be dependent of the type of research proposed (i.e. interventional clinical trial or natural history clinical research).

8. Draft and Final Clinical Study Reports

Upon completion of the clinical study/trial, a Draft Clinical Study Report should be prepared within one hundred twenty (120) calendar days after the database lock, as outlined in the data analysis plan, and submitted to the COR for review. A Final Clinical Study Report shall be submitted to the COR within thirty (30) calendar days of finalization of the report after the draft reports have been reviewed. At least one round of revision and resubmission for final approval is to be expected. The Clinical Study Reports shall include a complete description of the experimental design, protocol, methods, reagents, data analysis, and conclusions of studies as outlined by DMID or the FDA in the ICH E3 Guideline for Industry: Structure and Content of Clinical Study Reports, depending on the type of study (interventional vs. non interventional)
(http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/E3_Guideline.pdf).

9. Human Subject IRB Annual Report (Form 9OMB No 09900-263)

Within thirty (30) calendar days of each anniversary date of the effective contract award, submit Human Subject Annual Report to the COR and Contracting Officer (CO).

10. Clinical trial registration

The Contractor shall be responsible for registering the trial and posting of data in compliance with current Federal law with regards to clinical trials, unless otherwise negotiated with the COR and CO. http://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhoIsResponsibleForRegistering

11. Other Reports

Copies of other documents generated under the BAA may include draft and final annual reports for IND submissions, DMSB/SMC reports, and other study status reports. These will be negotiated post award and will be dependent on the type of study proposed.

B. Delivery Schedule

Delivery of other reports and deliverables will be proposed by the offerors in their technical proposal. They will be developed further after receipt of proposals as a result of finalization of the SOW and other terms and conditions of any resultant contract during negotiations.

C. Post-Award Requirements

Please note that the following POST-AWARD requirements will apply to all awards made under this BAA.

Offerors are instructed to address responsibility for complying with these requirements in the proposed Statement of Work for the Technical Proposal. Offerors are **NOT** required to submit documentation to address these post-award requirements in their technical proposals. Instructions for submitting documentation associated with post-award requirements will be provided during negotiations.

1. **Clinical Protocol Implementation Requirements**

a. Contractors must ensure that the clinical research is conducted in accordance with all Federal regulations, the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf) and, the International Conference on Harmonization ICH-E6-GCP guidelines (http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html). During negotiations further DMID guidance will be provided regarding requirements for the conduct of clinical trials.

b. Following DMID approval of the clinical protocol, the contractor shall secure Institutional Review Board (IRB) approval and submit to the COR, or the COR's designee, copies of all Essential Documentation, as defined by the ICH-E6-GCP (http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html, to conduct the final, COR approved, clinical trial for all participating clinical sites.

c. For interventional studies, the contractor is not expected to serve as the Investigational New Drug/Investigational Device Exemption (IND/IDE) sponsor. For those trials where an IND/IDE submission is required, DMID will serve as the IND/IDE sponsor and will assume responsibility for all required IND/IDE submissions. The necessity for an IND/IDE filing will be determined post-award. If an IND/IDE is necessary, the contractor shall be responsible for:

- assisting the COR and the DMID Office of Regulatory Affairs (ORA) as needed in preparing IND/IDE applications and amendments, pre-IND/IDE submission

briefing materials, and other documents for submission to regulatory agencies;
- participating in meetings and teleconferences with officials of the U.S. Food and Drug Administration (FDA); and assisting in responding to FDA comments, questions and requests for additional information relative to IND/IDE applications/studies.

2. **Clinical Research Support Services**

The DMID/NIAID stratifies clinical research according to resources required to adequately ensure the safety of subjects. Research is stratified into three broad resource allocation categories: Low risk, medium risk and high risk.

NIAID defines high-risk clinical trials as those that have one or more of the following attributes:
- involves a non-routine intervention, that is, an intervention that would not otherwise be provided for the condition under study in the local facility where the study is being conducted;
- involves administration of an unlicensed product; or
- involves administration of a licensed product for an unapproved indication.

For high-risk clinical trials under DMID-held INDs, DMID will provide the data management, clinical site monitoring and regulatory document review. The contractor shall be responsible for the administrative oversight of the study, managing document development and ensuring compliance of sites with study requirements and DMID oversight. The contractor shall also be responsible for assisting the COR and his/her designees in scheduling study initiation activities, planning agendas and distributing study-specific materials, including Final Protocols and protocol-related documents, to participating clinical research site personnel. The contractor shall instruct the sites on protocol-specific requirements and procedures. The contractor shall interact and cooperate with other DMID contractors responsible for the data management system, clinical site monitoring and essential regulatory document review.

For medium and low risk studies or for high risk studies that do not require an IND, the COR will determine, on a study-specific basis, the types of study initiation activities that may be required prior to protocol implementation. Such determinations will be based on an assessment of protocol risk, the characteristics of individual participating clinical research sites, and/or other protocol-related features. Study initiation activities shall be conducted via meetings, videoconferences or teleconferences as determined by the COR in consultation with the Principal Investigator. The contractor shall be responsible for assisting the COR and his/her designees in scheduling study initiation activities and developing study-specific materials; planning agendas and distributing study-specific materials, including Final Protocols and protocol-related documents, to participating clinical research site personnel; and making presentations on protocol-specific requirements and procedures. The Contractor shall interact and cooperate with other DMID contractors providing clinical research support or safety oversight.

Clinical site and study monitoring visits during the conduct of interventional clinical trials will be conducted by DMID staff and/or DMID Clinical Research Operations Management Support (DMID-CROMS) contractors. Clinical site and

study monitoring for non-interventional studies are the responsibility of the contractor. Additional or supplemental clinical site monitoring may be conducted by DMID staff or DMID-CROMS. The contractor shall make all relevant study personnel, documentation, facilities and equipment, available for such site visits and shall implement any COR-approved corrective actions resulting from such monitoring.

3. **Safety Oversight Requirements**

The "NIH Policy for Data and Safety Monitoring" (1998)[1] requires data and safety monitoring for all NIH supported clinical trials to ensure the safety of participants and the validity and integrity of the data, at a level consistent with the type of study proposed. The DMID/NIAID will determine the level of safety oversight needed for the proposed study. The DSMB or SMC will be convened by authority of DMID and is advisory to DMID and the study team. For Interventional studies and in select other studies where study procedures represent a significant risk, the DMID Office of Clinical Research (OCRA) also will assign a DMID medical monitor to review and evaluate information relevant to the product safety throughout the development and implementation of the protocol. Additional information on the role of the medical monitor may be found at: http://www.niaid.nih.gov/LabsAndResources/resources/DMIDClinRsrch/Documents/medicalmonitor.pdf .
For interventional studies, the contractor (and all clinical sites) have the responsibility to report adverse events (initial and follow-up) to DMID's centralized safety reporting at DMID-CROMS. For more information on the pharmacovigelence requirements please refer to: http://www.niaid.nih.gov/LabsAndResources/resources/DMIDClinRsrch/Pages/pharma.aspx
The contractor shall interact and cooperate with DMID contractors responsible for safety oversight.

4. **Contractual Commitments**

Upon award of a contract, the contractor shall be required to make legal commitments through acceptance of Government contract clauses. The outline that follows is illustrative of the types of provisions required by the Federal Acquisition Regulations (FAR) that shall be included in the contract. This is not a complete list of provisions to be included in contracts, nor does it contain specific wording of these clauses. Copies of complete terms and conditions applicable to your contract will be provided during negotiations.

a) Standards of Work. Work performed under the contract must conform to high professional standards.
b) Inspection. Work performed under the contract is subject to Government inspection and evaluation at all times.
c) Termination for Convenience. The Government may terminate the contract at any time for its convenience if it deems termination to be in its best interest, in which case the contractor would be compensated for work performed and for reasonable termination costs.
d) Disputes. Any dispute concerning the contract that cannot be resolved by agreement shall be decided by the Contracting Officer with right of appeal.

e) Equal Opportunity. The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.
f) Affirmative Action for Veterans. The contractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era.
g) Affirmative Action for Handicapped. The contractor will not discriminate against any employee or applicant for employment because he or she is physically or mentally handicapped.
h) Gratuities. The Government may terminate the contract if any gratuities have been offered to any representative of the Government to secure the contract.
i) American-made Equipment and Products. When purchasing equipment or products under a contract award, the contractor shall purchase only American-made items whenever possible.
j) Examination of Records. The Comptroller General (or a duly authorized representative) shall have the right to examine any directly pertinent records of the contractor involving transactions related to this contract.
k) Default. The Government may terminate the contract for default if the contractor fails to perform the work described in the contract and such failure is not the result of excusable delays.
l) Contract Work Hours. The contractor may not require an employee to work more than eight hours a day or forty hours a week unless the employee is compensated accordingly (i.e., overtime pay).
m) Covenant Against Contingent Fees. No person or agency has been employed to solicit or secure the contract upon an understanding for compensation except bona fide employees or commercial agencies maintained by the contractor for the purpose of securing business.
n) Patent Infringement. The contractor shall report each notice or claim of patent infringement based on the performance of the contract.

5. **Electronic and Information Technology (SECTION 508)**

This is applicable if you are proposing electronic and information technology (EIT) in your proposal:

Electronic and Information Technology Accessibility, **HHSAR 352.239-73(a)** (January 2010)

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit:
    1. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
    2. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

b. Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility standards. Information about Section 508 visions is available at http://www.section508.gov/ . The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards .

c. The Section 508 accessibility standards applicable to this solicitation are identified in the Statement of Work/Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Evaluation Template may be found on the HHS Web site (http://www.hhs.gov/web/508/contracting/technology/vendors.html).

d. Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 accessibility standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government -- i.e., after award of a contract/order, that products or services delivered do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor and at its expense.

VI. TECHNICAL PROPOSAL INSTRUCTIONS

It is recommended that offerors use the format below to prepare the Technical Proposal and present all information in the order specified.

FORMAT FOR TECHNICAL PROPOSAL

Offerors are advised to give careful consideration to the Broad Agency Announcement Introduction, Background and Technical Objectives, all reference materials and attachments, the Technical Proposal Instructions, the Technical Evaluation Criteria, and the BAA as a whole in the development of their Technical Proposals. The technical proposal should include sufficient descriptions of the proposed research, including background supporting the scientific justification and feasibility of the proposed research plan, the clinical approach to be used, and the general methods for analysis of outcome measures. Information should be included on the feasibility of the approach and specific

information demonstrating an understanding of clinical research or clinical trial management and implementation requirements. Finally all offerors shall include a proposed Statement of Work (SOW) as part of the technical proposal that specifies deliverable work products that correspond to concrete steps that will be undertaken in the delivery of complete research project.

1. **PROPOSAL TITLE PAGE** Include the BAA title and number, name of organization, DUNS number, identify as the Technical Proposal, identify if the proposal is an original or a copy, and date of proposal.

2. **TABLE OF CONTENTS** (Each offeror's Technical Proposal shall include a Table of Contents.)

3. **OVERVIEW** (suggested 2-page maximum – included in total page limitation)

   Provide a brief description of the proposed project including:

i. Identification and synopsis of the proposed clinical study or trial, including the rationale for the study, the proposed trial design, identification of the disease and the population to be studied. For interventional trials, include a brief description of the product to be evaluated;
ii. Identification of the offeror and proposed key personnel with degrees, titles, and roles;
iii. Identification of proposed subcontractors and any key subcontractor personnel with degrees, titles, and roles; and
iv. A brief description of the facilities and other resources to be made available by the offeror and any proposed subcontractors.

4. **SCIENTIFIC AND TECHNICAL APPROACHES**

A. CLINICAL RESEARCH PLAN

Describe, in sufficient detail, all aspects of your clinical project from development through conduct and analysis. Technical proposals shall include a detailed description of the proposed clinical research, including: the background and rationale for the study, the overall objectives, the proposed study design and endpoints, the study population, and the rationale for the approach. Describe your capability, past experience, plans for recruitment and retention of subjects for clinical research, as well as your access to the required study population. Identify anticipated problems and difficulties that may arise in recruiting and retaining these subjects and discuss proposed approaches to overcome or minimize such problems and difficulties. Provide a rationale for the selection of clinical sites proposed and describe how those sites will be managed. If an interventional product is to be used, describe the product, including its development status and safety profile. Provide documentation of acquisition of the study products (active and placebo). For **investigational agents that have not been marketed**, provide a letter from the pharmaceutical manufacturer of the investigational product, stating that they will provide the test articles (active and placebo as necessary) and understand the NIAID requirements under which the study will be conducted. If a pharmaceutical partner is identified, provide evidence of an agreement between the offeror and the pharmaceutical partner of the following understandings: DMID will hold the IND and will assume all responsibility and oversight roles, the company will be granted a copy of the dataset and the clinical study report at the end of the study, ownership of Intellectual

Property will be determined by US law, agreement by the pharmaceutical partner to provide insurance or self-insure to cover the cost of treatment or stabilization of adverse events for products received in accordance with the protocol, and the company may participate as a member of the protocol team but will not have final authority over the conduct of the study.

Describe safety monitoring activities that will be undertaken relevant to the type of study proposed. Identify critical laboratory studies (safety and efficacy) and assays for endpoint assessments, as necessary.

B. STATISTICAL, DATA, AND QUALITY MANAGEMENT

Describe in sufficient detail for all study types (e.g., natural history, clinical research or interventional IND studies),

1. Statistical Plan and Support

    a) For all studies, provide a brief description of the statistical support, plan and analysis appropriate for the proposed clinical research project, including but not limited to, power calculations and enrollment needed to achieve objectives. The plan should be consistent with the type of study proposed.

        Note: For IND studies, a formal statistical analysis plan (SAP) will be required prior to enrolling subjects on the study. The contractor shall be responsible for working with the NIAID DMID Statistical Data and Coordinating Center (SDCC) to develop and update the plan as needed.

2. Data Management Support and Plan

    For non-IND studies

    a) Describe proposed plans and procedures to be implemented to ensure appropriate objectivity and independence in carrying out statistical support and data management services.
    b) Describe the data management systems and quality control systems that will be used for the proposed study and procedures for data entry and validation, documentation of data corrections, routine maintenance and backup, transmission of data, the data reporting and exporting system, access control and confidentiality, and data retrieval and disaster recovery.
    c) Describe how the data shall be presented to DMID/NIAID and what provisions shall be made available for DMID to query the data.
    d) Describe plans and procedures to provide security against anticipated risks, including loss of confidentiality of subject electronic records and data summaries.

    Note: <u>For interventional studies that will be conducted under IND</u>, the NIAID DMID Statistical Data and Coordinating Center (SDCC) will be responsible for the operation of a central data management system for the receipt, storage, tracking and retrieval of all clinical and laboratory data, and for implementing quality assurance/quality control procedures to ensure the accuracy, completeness and timeliness of clinical trial data. Training in the use of the central data management system shall be provided to clinical

site personnel by the DMID SDCC contractor. Information about the current NIAID SDCC contractor can be found here: http://www.niaid.nih.gov/LabsAndResources/resources/dmid/Pages/sdcc.aspx

3. Quality Management

a.) Describe the plans and procedures to be implemented to ensure the quality and integrity of the data collection system from the clinical site through database entry and storage, as appropriate for the type of study proposed.

C. PROJECT MANAGEMENT PLAN

1. Overall Project Management

a. Describe how the project will be organized and managed, including administrative and scientific/clinical structures.
b. Provide a Staffing Plan, indicating role descriptions, level of effort of key scientific and technical personnel, and clear lines of authority and responsibility for the personnel, including all proposed subcontractors and clinical performance site locations, both domestic and international, as applicable. Include a diagram of the proposed organizational/management structure for the project.
c. Describe project management systems that will be used to track activities and to keep multiple activities on time and within budget. The plan should include a description of quality control methods that will be used to ensure the effective initiation, implementation, management and oversight of contract activities.
d. Discuss and outline communication, monitoring, and management of the project, both internally and externally (at subcontractor facilities). Discuss plans for sharing information with the COR and CO.
e. Describe plans for the receipt, shipping, storage, handling and testing of any clinical specimens to be evaluated.

2. Acquisition and Management of Subcontractors

Describe plans to secure, execute, and manage any subcontractor services in accordance with the requirements established by Federal contracting regulations (FAR Clause 52.244.2). Discuss proposed plans to assess subcontractor performance, identify problems and deficiencies, and develop and implement corrective actions when necessary.

3. Clinical Site Monitoring and Essential Regulatory Documents Collection

For all studies provide a general description of plans and procedures necessary to oversee clinical sites for human subject protections, essential documents and data integrity.

NOTE: For interventional studies and high risk studies, NIAID/DMID will establish plans and procedures appropriate to the proposed clinical study to monitor all participating clinical sites to verify that the rights and well-being of the subjects are protected, trial data are accurate, complete and verifiable, and the conduct of the trial is in compliance with Good Clinical Practice (GCP), International

Conference on Harmonization (ICH) guidelines, the approved protocol, and all applicable regulatory requirements. For these studies, Clinical site and study monitoring visits during the execution of interventional clinical trials will be conducted by DMID staff and/or DMID-designated entities. The contractor shall be required to provide to the DMID and/or DMID–CROMS all essential documents related to the protocol that are required for oversight and verification**.**

For low and medium risk non interventional studies, DMID-CROMS may perform target monitoring and assist with collect of all essential regulatory documents as indicated by the needs of the study and approved by the COR.

D. FACILITIES, EQUIPMENT AND OTHER RESOURCES

As appropriate, the Technical Proposal shall document the availability and adequacy, including safety and security, of facilities, equipment, space, and other resources necessary for performance of the contract, including:

1) Ownership/lease of facilities, including availability of proposed facilities for the duration of the contract;
2) Plan for obtaining, adding or deleting facilities as necessary due to progress or performance issues that arise during the course of the project;
3) Clinical facilities for patient screening, enrollment, administration of study product(s), monitoring and follow-up, including inpatient facilities and emergency medical facilities, where necessary, for the conduct of the proposed clinical trial;
4) Laboratory facilities and equipment for performing protocol-specific tests to determine patient eligibility and monitor safety;
5) Pharmacy facilities for receipt, storage, dispensing, and inventory of study product(s) (Note: Study products will be shipped to the pharmacies from DMID's Microbiology and Infectious Diseases Biological Resource Repository (BRR));
6) Facilities for the storage, under appropriate conditions, of clinical specimens, as required for the proposed clinical trial;
7) Areas for the secure storage of patient records, including procedures for secure access for designated personnel only;
8) Provision of computers at all clinical sites for the secure entry and maintenance of clinical and laboratory data; and
9) Data management facility for receipt, verification, storage and retrieval of clinical and laboratory data as necessary to support the type of study proposed.

E. SCIENTIFIC AND TECHNICAL TEAM

The Technical Proposal shall include all information relevant to documentation of individual training, education, experience, qualifications, and expertise, as well as availability necessary for the successful completion of all contract requirements. Clearly identify who is proposed as Key Personnel. Limit CVs to 3 pages, provide selected references for publications relevant to the scope of this BAA, and include experience with projects of similar scope, size and complexity carried out by the offeror and any proposed subcontractors over the past 5 years.

F. ORGANIZATIONAL EXPERIENCE

Include in the technical proposals a description of at least two (2) similar projects performed by your organization that are of comparable size and scope and/or related

to the effort proposed in response to this BAA. The projects may be either completed or ongoing.

5. STATEMENT OF WORK

Offeror(s) are required to provide a Statement of Work (SOW) in their Technical Proposal. The SOW shall be developed by each offeror and shall consist of two parts: (1) Scope and Overall Objectives, and (2) Technical Requirements.

The SOW to be completed under contract funding must be reasonably completed within the 5-year maximum period of performance. The SOW for the proposed clinical study/trial submitted with the Technical Proposal will be subject to negotiations. If an award is made, the SOW shall be updated and approved by the COR and the Contracting Officer prior to the initiation of any activities related to its execution. The SOW shall be updated upon a change in work plan. The updated SOW must be approved by the COR and the Contracting Officer prior to the initiation of any activities related to its execution.

The SOW shall include:

1. A statement of the key objectives/aims of the clinical research to be accomplished and key milestones for the project implementation;
2. A description of tasks required for the conduct of the proposed clinical research;
3. A statement and description of fundamental tasks required for effective project management and oversight of the clinical research within each performance period;
4. Estimated enrollment per performance period;
5. Tasks required for implementation of data collection and management;
6. A description of the tasks required for site management and communication;
7. A statement of agreement to work with other DMID contractors providing clinical research support and safety oversight;
8. A list and description of all items to be delivered to the Government at each stage in the product development process during the performance of the contract and a timeline for delivery;
9. A statement that the study will be conducted in accordance with all applicable laws, regulations and guidances;
10. Proposed timelines for all stages required to develop and complete the clinical research study/trial, as noted above, encompassing protocol development, enrollment, protocol implementation, clinical trial completion, and analysis of final study data and development of final clinical study reports;
11. A Technical Proposal Cost Summary, to include: a list of all subcontracts by activity (for example, laboratory assessments or clinical trial sites) and a budget for each stage of the proposed study (direct plus indirect).
    Note: Offerors proposing subcontracts and/or consultants to perform portions of the SOW should clearly identify the specific tasks for which they plan to utilize subcontractors and/or consultants, as well as the method and level of integration/coordination between the prime contractor and all proposed subcontractors and/or consultants, and the expected advantages of such an approach. Processes for subcontractor and consultant identification, selection, management and evaluation should be described. Expected deliverables associated with consulting services should be clearly delineated. Subcontractors and consultants selected after award will require Contracting Officer approval. The technical proposal must include direct cost and resources information, such as labor-hours and categories, materials, subcontracts, travel, etc., and associated costs for each task so that the offeror's understanding of the project may be

evaluated (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf). However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose the technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions;

12. A task-linked budget providing a breakdown of direct costs linked to each stage of accomplishments, task and subtask contained on a detailed chart. The lowest level of tasks or subtasks for each activity for which budget is assigned will be determined by the offeror. However the budget plan, based on the task-linked budget must provide for feasible execution, management and oversight. The budget linked to activities at the lowest level should include a budget for all subordinate activities. The timeline should identify summary tasks and subtasks. A table must be provided to show how the major tasks would be divided into different funding periods by fiscal year.

STATEMENT OF WORK FORMAT

Provided below is an outline of the format that is recommended to be used by all offeror(s) in the preparation of their SOW. The headers and sub-headers may be adjusted to match the requirements as proposed in each offeror's individual Technical Proposal.

Contracts awarded as a result of this BAA will include the SOW proposed by the offeror, as negotiated and accepted by the Government. Offeror(s) will be required to perform the activities and provide the resources appropriate to the scope of their specific negotiated SOW.

The opening paragraph under the Technical Requirements section of the SOW shall be followed by a description of all activities that the Contractor shall perform after the award of the contract. The Technical Requirements shall include all activities required to effectively implement the project and shall include a description of all items to be delivered to the Government during performance of the contract, such as progress reports, financial reports, end products, and other deliverables, along with a timetable for their delivery.

Each offeror shall provide detailed specifications of the requirement utilizing the following sample outline of tasks and subtasks. Any tasks or subtasks that are not applicable to your proposed effort should be deleted. Any tasks or subtasks specific to your proposed effort not addressed below shall be added.

Offerors are advised to limit the amount of proprietary data or markings in their SOW. The final negotiated SOW will be incorporated into the contract upon an award and may be subject to release to the public. If the SOW does include proprietary data or markings, offeror(s) are advised to clearly mark these portions and provide an explanation why these data/markings are proprietary.

> Note: Contract activities will be divided into manageable non-severable defined tasks, with duration no longer than two years. Initial funding will be for the Base Period only. Funding of subsequent tasks will be funded by Options. Each Option will be fully funded when exercised and will be dependent on successful completion of research study critical milestones,

including United States Government (USG) acceptance of associated deliverables when applicable.

The Offeror's proposed Statement of Work should begin as follows:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the SOW below:

Offerors are advised to use the headings provided below in preparing the proposed SOW, as appropriate to the proposed research.

A. Scope and Overall Objectives

B. Technical Requirements

1. Clinical Protocol and Supporting Documentation Development
2. Clinical Research Conduct and Implementation
3. Enrollment Plan
4. Laboratory Assessments
5. Data Management
6. Project Management and Oversight of Implementation
7. Reports and Deliverables
8. Operational Meetings and Meeting Support
9. Agreements and Understandings

6. OTHER CONSIDERATIONS

A. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)

1. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

2. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any Subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

3. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with

any of the requirements and/or standards stated in paragraphs (1) and (2) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone, with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Human Subject Assurances.
(End of clause)

B. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the Principal Investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named individual and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as Subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

C. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract,

were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

D. SHARING RESEARCH DATA

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

Offerors will be required to submit a data sharing plan for review and approval prior to award of any Contract. Any changes to that plan will also require NIH approval.

E. HIGHLY PATHOGENIC AGENTS

The work being conducted under this contract may involve a Highly Pathogenic Agent (HPA). The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

(http://www.cdc.gov/biosafety/publications/index.htm under "Publications);

2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or

3. The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

F. INFORMATION SECURITY REQUIREMENTS

The government will require each offeror selected for negotiations to submit an E-Authentication Risk Assessment, E-Authentication Threshold Analysis and a System Security Plan with the their Final Proposal Revision to be reviewed by the Information System Security Officer (ISSO) and Contracting Officer.

VII. BUSINESS PROPOSAL INSTRUCTIONS

In order to minimize the government's financial risk, contract activities may be divided into manageable time frames with initial funding of only the Base Activities. Funding of additional work will be funded by Options. Each Option will be fully funded when exercised and will be dependent upon successful completion of critical predecessor activities, including USG acceptance of associated deliverables, when applicable. The critical predecessor activities should constitute Go/No Go criteria for successor activities. The contract budget will be aligned with the Base Activities, Options and associated tasks identified in the proposal.

Consequently, Business Proposals must provide a detailed task-linked budget that consists of a breakdown of total costs (direct costs, indirect costs, and fees) linked to the Base period, and each Option, task and subtask (as applicable). Budget will be linked to tasks down to a level that the offeror considers reasonable and manageable, but will also facilitate cost accountability and proper contractor and government oversight and management of cost/performance issues.

A summary budget reflecting the total costs over the period of performance of the proposed contract shall be provided in the same "Breakdown of Proposed Estimated Costs (plus fee) and Labor Hours" format (see: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx).

The proposed timeline will consist of summary tasks, tasks and subtasks, for all activities covering the initiation, and conduct and completion of all clinical research activities. The clinical research activities will be planned and structured such that the Base period and each individual Option will be performed within the entire period of performance of the contract. The lowest level of tasks or subtasks for each activity for which a budget is assigned will be determined by the offeror. However the budget plan, based on the task-linked budget must provide for feasible execution, management and oversight. A budget linked to activities at the lowest level should include a budget for all subordinate activities.

1) General Instructions

Offerors must provide the following information on the first page of the Business Proposal:

a) Solicitation and/or amendment number;
b) Name and address of offeror;
c) Name and telephone number of point of contact;
d) Name of contract administration office (if available);
e) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
f) Proposed cost; profit or fee; and total;
g) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
h) Whether your organization is subject to cost accounting standards; whether your organization has submitted a Cost Accounting Standards Board (CASB) Disclosure Statement, and if it has been determined to be adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or Cost Accounting Standards (CAS), and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
i) The following statement: This proposal reflects our estimates and/or actual costs as of this date. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price.
j) Date of submission; and
k) Name, title and signature of authorized representative.

2) Certified Cost or Pricing Data

As part of the specific information required, you must submit, with your proposal, certified cost or pricing data (as defined at FAR 2.101). You must clearly identify on your cover sheet that certified cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including;

- The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
- The nature and amount of any contingencies included in the proposed price.

In submitting your proposal, you must include an index, appropriately referenced, of all the certified cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed line item, using the appropriate format prescribed in section 4 - "Formats for Submission

of Line Item Summaries'' below. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

After final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

3) Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

a) Direct Labor. Provide a time phased (e.g. monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates of percentage of direct labor.

b) Other Costs. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

c) Materials and services. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when certified cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own certified cost or pricing data submissions for subcontracts. Submit the subcontractor certified cost or pricing data as part of your own certified cost or pricing data as required in paragraph d below. These requirements also apply to all subcontractors if required to submit certified cost or pricing data.

d) Obtain certified cost or pricing data from prospective sources for those acquisitions, such as subcontracts, purchase orders, material order, etc. (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of certified cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $12.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. Also submit any information reasonably required to explain your estimating process (including the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data, and the nature

and amount of any contingencies included in the price). The Contracting Officer may require you to submit certified cost or pricing data in support of proposals in lower amounts. Subcontractor certified cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For inter-organizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the certified cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's certified cost or pricing data is required as described in this paragraph, it must be included, along with your own certified cost or pricing data submission, as part of your own certified cost or pricing data. You must also submit any other certified cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

e) Royalties. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:
   i. Name and address of licensor;
   ii. Date of license agreement;
   iii. Patent numbers;
   iv. Patent application serial numbers, or other basis on which the royalty is payable;
   v. Brief description (including any part or model numbers of each contract item or component on which the royalty is payable);
   vi. Percentage or dollar rate of royalty per unit;
   vii. Unit price of contract item;
   viii. Number of units;
   ix. Total dollar amount of royalties.

f) Adequate Price Competition. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) priced on the basis of adequate price competition. For inter-organizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205 26(e)).

g) Indirect Costs. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.202 and 31.205-37).

h) Facilities Capital Cost of Money. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB CMF and show the calculation of the proposed amount (see FAR 31.205 10).

4) Formats for Submission of Line Items Summaries

The detailed breakdown shall be in the format as shown on the form Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours. For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished. See (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx).

General Information

a) There is a clear distinction between submitting certified cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of certified cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of certified cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

b) By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

5) Travel Costs/Travel Policy

a) Travel Costs - Commercial

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA) (http://www.gsa.gov/portal/content/104877). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) Travel Policy

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

6) Intellectual Property

The awardee is solely responsible for the timely acquisition of all appropriate propriety rights, including intellectual property rights, and all materials needed for the awardee to perform the project. Before, during, and subsequent to the award, the U.S. Government is not required to obtain for the awardee any propriety rights, including intellectual property rights, or any materials needed by the awardee to perform the project.

The awardee is required to report to the U.S. Government all inventions made in the performance of the project, as specified by 35 U.S.C. Sect. 202 (Bayh-Dole Act).

VIII. SPECIAL CONTRACT REQUIREMENTS

Any award(s) resulting from this BAA shall include the following requirements.

1. **Information and Physical Access Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

   IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Business Proposal entitled "Information Security."

   The Homeland Security Presidential Directive (HSPD)-12 and the Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source.

   A. **HHS-Controlled Facilities and Information Systems Security**

      a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

      b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:
         1. HHS-OCIO Information Systems Security and Privacy Policy (http://www.hhs.gov/ocio/policy/#Security)
         2. HHS HSPD-12 Policy Document, v. 2.0 (http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf)
         3. Information regarding background checks/badges (http://idbadge.nih.gov/background/index.asp)

c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

[ ] **Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] **Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[ ] **Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

d. The personnel investigation procedures for Contractor personnel require that the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

As part of its proposal, and if the anticipated position sensitivity levels are specified in paragraph (d) above, the Offeror shall notify the Contracting Officer of (1) its proposed personnel who will be subject to a background check/investigation and (2) whether any of its proposed personnel who will work under the contract have previously been the subject of national agency checks or background investigations.

Upon award, the Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).

g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. **Standard for Security Configurations, HHSAR 352.239-70,** (January 2010)

a. The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see http://nvd.nist.gov/fdcc/index.cfm) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

Note: FDCC is applicable to all computing systems using Windows XPTM and Windows VistaTM, including desktops and laptops - regardless of function - but not including servers.

b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:

c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security

Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see http://scap.nist.gov/validation . The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.

d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.

e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.

f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.

g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

C. **Standard for Encryption language, HHSAR 352.239-71,** (January 2010)

a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).

b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see http://csrc.nist.gov/cryptval/) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.

c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.

d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).

e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.

f. The Contractor shall ensure that its subcontractors (all tiers) which perform work under this contract comply with the requirements contained in this clause.

D. **Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72,** (January 2010)

a. **Applicability** . This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.

b. **Contractor responsibilities** . The Contractor is responsible for the following:

1. Protecting Federal information and Federal information systems in order to ensure their -
    a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
    b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
    c. Availability, which means ensuring timely and reliable access to and use of information.
2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is

outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.

c. **Contractor security deliverables** . In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:

1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.
    a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:
        i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.
        ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.
        iii. HHS-OCIO Information Systems Security and Privacy Policy.

2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor

implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.

3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199** Assessment**)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.

4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.
    b. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.
    c. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:
        i. Annual testing of the system contingency plan; and
        ii. The performance of security control testing and evaluation.

d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.

e. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and

networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.

f. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -

1. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
2. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.

h. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.

i. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.

j. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.

k. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of Clause)

Note: The NIST Special Publication SP-800-26 cited in subparagraph c.1.a.(ii) of this clause has been superseded by NIST SP 800-53A, "Guide for Assessing the Security Controls in Federal Information Systems and Organizations" for use for the assessment of security control effectiveness. See http://csrc.nist.gov/publications/PubsSPs.html to access NIST Special Publications (800 Series).

E. Additional NIH Requirements

1. SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)

a. Information Type:
[X] Administrative, Management and Support Information:
[ ] Mission Based Information:

b. Security Categories and Levels:

Confidentiality Level:	[X] Low	[ ] Moderate	[ ] High
Integrity Level:	[ ] Low	[X] Moderate	[ ] High
Availability Level:	[X] Low	[ ] Moderate	[ ] High
Overall Level:	**[ ] Low**	**[X] Moderate**	**[ ] High**

c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

2. INFORMATION SECURITY TRAINING

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, the contractor shall comply with the below training:

a. Mandatory Training

i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a)(4), shall complete the NIH Computer Security Awareness Training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.

ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

b. Role-based Training
HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance about "NIH Information Security Awareness and Training Policy," at:
https://ocio.nih.gov/InfoSecurity/Policy/Documents/Final-InfoSecAwarenessTrainPol.doc.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COR and/or Contracting Officer upon request.

c. Rules of Behavior
The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior (https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx), which are contained in the NIH Information Security Awareness Training Course http://irtsectraining.nih.gov.

3. PERSONNEL SECURITY RESPONSIBILITIES

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

a. In accordance with Paragraph (h) of HHSAR 352.239-72, the Contractor shall notify the Contracting officer and the COR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.

b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.

c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.

d. **Commitment to Protect Non-Public Departmental Information and Data.**

The Contractor, and any subcontractors performing under this contract, shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with

provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

2. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $650,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9. See link: http://www.hhs.gov/asfr/ogapa/osbdu/Small%20Business/subcontractplan.html for an example of such a plan.

a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
c. The offeror understands that:
    1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof;
    2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract;
    3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed;
    4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer

in determining the responsibility of the offeror for award of the contract;

5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other;
6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:
   1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors;
   2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses;
   3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns;
   4. A description of the method used to develop the subcontracting goals;
   5. A description of the method used to identify potential sources for solicitation purposes;
   6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses;
   7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties;
   8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts;
   9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $650,000 adopt a plan similar to the plan agreed upon by the offeror;
   10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required

reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government;

11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

    For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

    HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

    33% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

3. Mentor-Protégé Program, HHSAR 352.219-70 (January 2010)

a. Large business prime contractors serving as mentors in the HHS Mentor-Protégé program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU)-approved mentor protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov . The mentor firm and protégé firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a $10,000 subcontract awarded to a protégé firm and provision of $5,000 of developmental assistance as $15,000 of developmental assistance.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

b.The program consists of:

1. Mentor firms-large businesses that: (i) demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and (ii) have a Mentor-Protégé agreement approved by HHS' OSDBU;

2. Protégé firms-firms that: (i) seek developmental assistance; (ii) qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small

businesses, small disadvantaged businesses, or woman-owned businesses; and (iii) have a Mentor-Protégé agreement approved by HHS' OSDBU; and

3. Mentor-Protégé agreements-joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

4. REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

a. Go to the **System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: http://www.sam.gov ; and

b. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL.**

If you are unable to access the SAM website, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IX. EVALUATION FACTORS FOR AWARD

1. GENERAL

The Government will make awards to the responsible offeror(s) whose proposals provide the best value to the Government and offer programmatic balance. For this solicitation, the technical proposal shall receive paramount consideration in the selection of the contractor(s). The evaluation will be based on the demonstrated capabilities of the prospective offerors in relation to the evaluation criteria as set forth herein. Each proposal must document the feasibility of successful implementation of the requirements of the BAA.

The estimated cost of an offer must be reasonable for the tasks to be performed and will be subject to a cost realism analysis by the Government.

All technical proposals will undergo evaluation by a peer review group also known as the Scientific Review Group (SRG).

Final selection of awards will depend upon the technical importance to the Agency programs, and availability of funds.

Offerors are reminded that the Technical Approach is evaluated within the context of "contribution and relevance to this program." For example, even though a proposal provides a clear, comprehensive technical plan for achieving a particular objective, if the plan is NOT within the context of the goals of this program, it will receive a low technical score regardless of the technical feasibility of the technical approach.

2. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data, or, if data sharing is not

possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

3. TECHNICAL EVALUATION CRITERIA:

The technical evaluation criteria are used by the peer review group when reviewing the technical proposals. As no common SOW exists, each proposal will be evaluated on its own merits as well as with regard to its relevance to the program goals rather than against other proposals for research in the same general area.

In considering the technical merit of each proposal, the criteria with weights assigned and sub-factors, which are of equal importance, are listed below. The overall adequacy of each proposal will be weighed in the context of the overall technical objectives of this BAA and the adequacy of the proposed technical approach in meeting the proposal's stated objectives. The following factors will be assessed:

TECHNICAL EVALUATION CRITERIA	WEIGHT
CRITERION 1: SCOPE AND SCIENTIFIC MERIT Relevance of the offeror's proposed research and approaches to the overall research and technical objectives articulated in this BAA (Section IIB Technical Objectives).	10
CRITERION 2: MERIT OF TECHNICAL PLAN/APPROACH • Adequacy, feasibility and appropriateness of the proposed clinical research plan to achieve the stated goals and objectives in the offeror's proposed SOW, including the suitability of the study design and implementation plans. • Adequacy of the plan to access the required patient populations to accomplish the SOW including the feasibility of the enrollment. • Adequacy and relevance of the general Data Management Plan (e.g., sound collection, security and dissemination of data) at a level suitable and feasible for the type of work proposed (e.g., interventional clinical trial vs. natural history study, etc.). • Adequacy of the proposed oversight and management of the clinical trial sites and implementation.	40

TECHNICAL EVALUATION CRITERIA	WEIGHT
CRITERION 3: SCIENTIFIC AND TECHNICAL PERSONNEL Appropriateness, adequacy and relevance of the documented education, training, experience, expertise, qualifications, and availability of the proposed scientific and technical personnel of the offeror and proposed subcontractors as demonstrated by: • Documented expertise of the PI or other key personnel in the conduct of clinical research as appropriate for the proposed SOW, including demonstrated knowledge of applicable regulatory guidelines; • Documented experience with projects of similar size and/or scope; • Documented qualifications, knowledge, experience, education, competence, and availability of the PI and other key scientific, project management and support personnel, provided by the Contractor or by subcontractors or consultants to carry out the proposed SOW; • The responsibilities and level of effort of all proposed staff of the offeror and any proposed subcontractors and consultants, including appropriate mix of staff, and expertise to carry out the proposed SOW.	25
CRITERION 4: PROJECT MANAGEMENT As required and/or suitable relative to the proposed specific SOW, the adequacy of the following: • The Project Management Plan for overall project organization, staffing, leadership, responsibilities, management, and lines of authority, organizational framework, including the plan to manage the work of consultants and/or subcontractors; • Proposed methods for coordination, monitoring, and central management of activities; • Plan to effectively communicate progress towards the proposed goals and objectives to the Government; • Plan to effectively communicate findings or important results to the Government and other entities as relevant to the proposed SOW.	15

TECHNICAL EVALUATION CRITERIA	WEIGHT
CRITERION 5: FACILITIES AND INFRASTRUCTURE • As required and/or appropriate for the offeror's proposed SOW, documented availability, suitability, capacity and adequacy of proposed facilities, equipment and other resources to successfully implement the proposed research. • Experience and capability of the organization, as well as proposed subcontractors and consults, if any, with similar projects of comparable size and scope. • Adequacy of the facilities to collect/store/distribute materials and/or clinical samples as necessary to achieve the objectives in the proposed SOW. • Adequacy of facilities to collect/store/manage clinical data in accordance with applicable regulations.	10
TOTAL POSSIBLE POINTS	100

4. EVALUATION OF OPTIONS

It is anticipated that any contracts awarded from this solicitation will contain option provisions and periods.

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

5. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the scientific and technical merit determination (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Negotiated Proposal. If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.